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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIN, JACK	

ART UNIT	PAPER NUMBER
3768	

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,529	BLAIR, ROBERT N.	
	Examiner	Art Unit	
	Jack Lin	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 04 February 2004 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/4/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on June 4, 2004 is acknowledged. The references listed therein have been considered.

Specification

2. The disclosure is objected to because of the following informalities:

Page 7, paragraph 27, line 4 – "with" should be omitted.

Page 11, paragraph 53, line 3 – "(104)" should be changed to "**104**".

Page 12, paragraph 55, line 7 – "n_2" refers to the refractive index of the sample and not of the ATR plate and should be changed to "n_1".

Page 18, paragraph 75, line 11 and paragraph 76, line 12 – reference number "230" is used to refer to the substrate and should be changed to "220" as previously used for the substrate.

Page 19, paragraph 78, line 10 – reference number "272" is used to refer to ridge and should be changed to "268" as previously used for ridge.

Appropriate correction is required.

Drawings

3. Figures 1, 2, and 9-11 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 3 is objected to because of the following informalities: Claim 3 should be changed from "...for about 3 about 25..." to "...for about 3 to about 25...". Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 25-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claim 25 specifies a method to determine an analyte level from a skin surface after a user's identity has been verified through a biometric feature. However, Claim 25 does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically, it does not appear to produce a tangible result because merely measuring a biometric feature and detecting and quantifying the reflected IR beam is nothing more than a computation within a processor. It fails to use or make available for use the result of the

determination to enable its functionality and usefulness to be realized. Additionally, the asserted practical application in the specification of the determination of an analyte level is for displaying the analyte concentration for the user. The practical application is not explicitly recited in the claims nor does it flow inherently therefrom. Therefore, Claim 25 appears non-statutory.

Claims 26-37 further limit Claim 25 but also do not specifically or inherently produce tangible results from the method steps.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-14, 18-19, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. (US Patent 6,421,548 B1) in view of Katarow (US Patent 6,643,531 B1). Berman et al. discloses a glucose level measurement device (col. 4, line 64) comprising of an IR source for emitting an IR beam into an ATR plate (col. 5, lines 1-2) that permits multiple internal

reflections (col. 5, lines 22-23), IR sensors for measuring absorbance of two specific regions of the IR spectrum (col. 5, lines 4-5), and a processor to transform the resulting signals into readable values (col. 5, lines 28-30). The IR source emits IR radiation at least in the region of the referencing wavelength and measuring wavelength (col. 5, lines 8-10), which for glucose are 8.25 to 8.75 micrometers for the referencing wavelength and 9.50 to 10.00 micrometers for the measuring wavelength (col. 5, 10-14). Berman et al. discloses applicant's basic inventive concept, a non-invasive analyte measurement device, substantially as claimed with the exception of a biometric sensor. Katarow shows this feature to be old in the non-invasive analyte measurement art. Katarow teaches a combination fingerprint and oximetry device (col. 1, line 8). Katarow shows this device to be able to obtain the fingerprint of a user, which may be transmitted to a remote memory store (col. 1, lines 57-59), so that it may be matched to the fingerprint of the user that had been previously stored in memory (col. 2, lines 4-6). Katarow further shows this device to contain a light source (col. 4, lines 42-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Katarow to modify the non-invasive analyte measurement device of Berman et al. by adding the biometric sensor of Katarow in order to allow for user identification prior to analyte measurement.

Regarding Claims 11-14, Katarow shows the fingerprint sensor to be adjacent to the photodector of the oximeter (Figures 5 and 6). Katarow further teaches that the fingerprint sensor and photodector may be arranged in other configurations to complement each other (col. 4, lines 62-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teachings of Katarow to incorporate the biometric sensor

with the ATR plate of the applicant's invention into different configurations in order to complement each other and optimize the device configuration.

10. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. in view of Katarow as applied to Claim 1 above, and further in view of Kramer (US Patent 6,512,381 B2) (incorporated by reference in entirely by applicant). Berman et al. in view of Katarow discloses applicant's basic inventive concept, a non-invasive analyte measurement device with an integrated biometric sensor, substantially as claimed with the exception of the composition of the biometric sensor assembly comprising of capacitive sensors. Kramer shows this feature to be old in the biometric sensors art. Kramer teaches capacitive sensors (col. 1, lines 19) comprising of a plurality of sensor cells arranged as an array to detect the presence of a ridge of a valley from the skin surface such as those present on a fingerprint (col. 1, lines 19-28), which provides more uniform sensitivity from one individual to another (col. 1, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Kramer to modify the non-invasive analyte measurement device of Berman et al. in view of Katarow by using the capacitive sensors of Kramer in order to provide more uniform sensitivity in the biometric measurement of one individual to another.

11. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. in view of Katarow as applied to claims 1 and 18-19 above, and further in view of Edwards (US Patent 4,429,413) (incorporated by reference in entirety by Katarow). Berman et al. in view of Katarow discloses applicant's basic inventive concept, a non-invasive analyte measurement device with an integrated biometric sensor, substantially as claimed with the exception of the composition of the biometric sensor assembly comprising photosensors. Edwards shows this

feature to be old in the biometric sensors art. Edwards teaches the use of solid state sensors for fingerprint verification (col. 8, line 23). It would have been obvious to one of ordinary skill in the art of the time of applicant's invention from the teaching of Edwards to modify the non-invasive analyte measurement device of Berman et al. in view of Katarow by using the solid state sensors of Edwards, which was incorporated by reference in entirety by Katarow, in order to provide another conventional method to identify the user of the analyte measurement device through the user's fingerprint.

12. Claims 25-27 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. (US Patent 6,421,548 B1) in view of Katarow (US Patent 6,643,531 B1) and Rowe et al. (US Patent 6,560,352 B2). Berman et al. discloses a method for determining the blood glucose level (col. 5, lines 35-36) comprising the steps of: contacting a skin surface with an ATR plate (col. 5, line 38), irradiating the skin surface with an IR beam having components at least in the region of the referencing wavelength and the measuring wavelength (col. 5, lines 39-41), and detecting and quantifying those referencing and measuring wavelength components in the reflected IR beam (col. 5, lines 42-44). The procedure can include further steps normalizing the referencing and measuring wavelength prior to contacting the skin (col. 5, lines 51-54) and of maintaining the skin surface on the ATR plate at an adequate pressure (col. 5, lines 45-48). Berman et al. discloses applicant's basic inventive concept, a method to non-invasively determine an analyte measurement, substantially as claimed with the exception of verifying the user through a biometric feature prior to determining the analyte measurement. Katarow and Rowe et al. shows this feature to be old in the non-invasive analyte measurement art. Katarow teaches a method of scanning a fingerprint of a user prior to the measurement of the oxygen

saturation via the oximeter (col. 1, lines 50-53). Katarow shows that the fingerprint of a user may be transmitted to a remote memory store (col. 1, lines 57-59) so that it may be matched to the fingerprints that had been previously stored in memory (col. 2, lines 4-6). Rowe et al. further teaches that biometric verification can be used to verify a person's identity prior to activating a particular machine (col. 2, lines 21-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Katarow and Rowe et al. to modify the non-invasive analyte measurement method of Berman et al. by adding the biometric sensing step of Katarow and Rowe et al. in order to allow for user identification prior to analyte measurement and control of the analyte measuring method based on the results of the identification procedure.

13. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. in view of Katarow and Rowe et al. as applied to Claim 25 above, and further in view of Kramer (US Patent 6,512,381 B2) (incorporated by reference in entirely by applicant). Berman et al. in view of Katarow and Rowe et al. discloses applicant's basic inventive concept, a method to use a biometric identification step prior to non-invasively determining an analyte measurement, substantially as claimed with the exception of using the capacitance of the skin surface to measure the biometric feature. Kramer teaches a method to detect fingerprints through measuring the capacitance of the ridges and valleys of the fingerprint (col. 1, lines 31-35), which provides more uniform sensitivity from one individual to another (col. 1, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Kramer to modify the non-invasive analyte measurement method with the biometric identification step of Berman et al. in view of Katarow and Rowe et al. by using the capacitive

sensing method of Kramer in order to provide more uniform sensitivity in the biometric measurement of one individual to another.

14. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. in view of Katarow and Rowe et al. as applied to Claim 25 above, and further in view of Edwards (US Patent 4,429,413) (incorporated by reference in entirely by Katarow). Berman et al. in view of Katarow and Rowe et al. discloses applicant's basic inventive concept, a method to use a biometric identification step prior to non-invasively determining an analyte measurement, substantially as claimed with the exception of using a reflected image to determine the biometric feature of a user. Edwards teaches a conventional method to detect fingerprint through the reflected image of a finger press (col. 1, lines 21-23). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Edwards to modify the non-invasive analyte measurement method with the biometric identification step of Berman et al. in view of Katarow and Rowe et al. by using the photo-detection method of Edwards, which was incorporated by reference in entirety by Katarow, in order to provide another conventional method to identify the user of the analyte measurement device through the user's fingerprint.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jack Lin
Art Unit 3768

ERIC F. WINAKUR
PRIMARY EXAMINER